As required by 21 CFR 807.92 (c) this 510(k) summary is prepared

Application Date:

SEP 13 2006

May 30, 2006

Applicant:

Spectrum Medical LLP
Delta Place,
27 Bath Road,
Cheltenham
GL53 7TH
United Kingdom

Official Correspondent:

Mr. Steve Turner
Managing Partner
Telephone: +44 (0) 1242 229231
Fax: +44 (0) 1242 229259
Email: Steve.Turner@spectrum-medical.co.uk

Proposed Device:

Blood Gas Monitor
Trade Name: Spectrum M2 Monitor
Classification Name: Monitor, Blood-Gas, On-Line, Cardiopulmonnary Bypass
21 CFR 870.4330, Product code: DRY

Predicate Device:

K931968 3M Health Care, Ltd CDI 100 Extracorporeal Hematocrit / Oxygen Monitoring Device

Description of Proposed Device:

The Spectrum M2 Monitor consists of a 10.4 inch high definition touch screen and two active measuring channels mounted into a flat panel unit. Sensor cables are used to connect one or both measuring channels to the external surface of extracorporeal blood line tubing. The sensor cable head contains a light emitting diode that sends light through the extracorporeal tube, which illuminates the flowing blood. The reflected spectra is collected by a fibre optic cable and quantified by a photo-detector contained within a spectrometer. These spectra are compared to reference spectra by the monitor's software to determine the oxygen saturation of the blood in the extracorporeal line.

The oxygen saturation levels for venous blood flow alone or both venous and arterial can be displayed by using one or both sensor channels. A trace of these oxygen levels are also displayed on the monitor. The M2 Monitor has been designed to self-detect the selected sensor and to automatically configure the required parameter display screens. The device can be configured by the trained clinician to alarm for set saturation levels on either channel and to record session data onto a memory card supplied with the system.

The M2 Monitor is powered from the AC Mains supply and also incorporates a battery back-up that automatically switches on in the event of an interruption to the mains power supply. The system weighs 4.5 kg and is supplied with a pole mount clamp.

Intended Use of Proposed Device

The intended use of the M2 Monitor is for the non-invasive continuous monitoring of oxygen saturation of the blood in an extracorporeal circuit. The device provides monitoring information to trained clinicians and can be configured by them to alarm for set saturation levels.

The difference in intended use between the proposed device and the predicate device is that the predicate device also measures the Hemaglobin and Hematocrit levels of the blood in the extracorporeal circuit. As this is an additional measurement offered by the predicate which is independent of the blood saturation measurement and is not claimed or implied by the proposed device this difference in intended use is not considered to raise any additional efficacy or safety concerns.

Summary of Technological Characteristics

The major difference in the technological characteristics of the proposed and predicate device is that the proposed device provides a completely non-invasive measurement of the blood in the extracorporeal bloodline while the predicate involves the use of a cuvette inserted into the blood line tubing. Performance data has been provided that shows that the proposed device achieves equivalent accuracy for the measurement of oxygen saturation of the blood to the predicate device.

Substantial Equivalence Determination

The M2 Monitor has an intended use that is also featured in the predicate device. Performance data has been provided to show that the M2 Monitor can measure the oxygen saturation of blood in extracorporeal blood ines to an equivalent accuracy to its predicate device. The M2 Monitor is therefore considered substantially equivalent to its predicate device for the monitoring of oxygen saturation in extracorporeal blood line tubing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2006

Spectrum Medical LLP
c/o Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K062468
Trade Name: Spectrum M2 Monitor
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary Bypass On-line Blood Gas Monitor
Regulatory Class: Class II (two)
Product Code: DRY
Dated:August 2, 2006
Received: August 24, 2006

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062468

Device Name: Spectrum M2 Monitor

Indications for Use:

The M2 Monitor is intended as a device for the non-invasive continuous monitoring of oxygen saturation of the blood in an extracorporeal circuit. The device provides monitoring information to trained clinicians and can be configured by them to alarm for set saturation levels.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062468